

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

JAMES DALE SIMS, an Individual,
and LINDA SIMS, an Individual,

Plaintiff,

SMITHKLINE BEECHAM
CORPORATION d/b/a
GLAXOSMITHKLINE,

Defendants.

CV 08

CIVIL NO

0364

COMPLAINT AND JURY DEMAND

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiff, JAMES DALE SIMS and LINDA SIMS (hereinafter referred to as "Plaintiff"), for their multiple causes of action, by through their undersigned attorneys, hereby sues the defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, a Pennsylvania Corporation which has its principle place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19101, alleges and states the following:

STATEMENT OF THE CASE

1. This is an action brought by Plaintiff to recover damages for personal injury, restitution, refund and/or for equitable, injunction relief, following ingestion of Avandia, as the direct and proximate result of the wrongful conduct of the Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, (herein

referred to as "Defendant" or "GSK"), in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the widely-used diabetes prescription drug Avandia (rosiglitazone).

PARTIES AND JURISDICTION

2. Plaintiff, suffered a myocardial infarction on January 18, 2006 as a result of his use of Avandia and Defendant's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, promoting, marketing, distributing, labeling, and/or sale of Avandia.

3. Jurisdiction exists as against Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, pursuant to:

a. 28 U.S.C. Section 1332, in that, at all times relevant hereto, Plaintiff was a domiciliary and citizen of the state of California, with his true, fixed and permanent home and residence at 10540 Croetto Way, #1, Rancho Cordova, California 95670; and the Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, is a Pennsylvania corporation with its principal business and address at 1 Franklin Plaza, Philadelphia, Pennsylvania; and Defendant regularly conducts business in the State of California; and the amount in controversy exceeds the sum of \$75,000.00 exclusive of interests and costs.

b. 28 U.S.C Section 1391, in that jurisdiction is founded only diversity of citizenship, and the Judicial District of the Northern District of California is the Judicial District in which a substantial part of the events or omissions giving rise to the claim occurred.

4. That at all times hereinafter mentioned, upon information and belief, Defendant SMITHKLINE BEECHAM CORPORATION, was and still is a corporation organized and existing under the laws of the State of Pennsylvania.

5. That at all times hereinafter mentioned, upon information and belief, Defendant SMITHKLINE BEECHAM CORPORATION, was and still is a foreign corporation authorized to do business in the State of California.

6. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION, was and still is a business entity actually doing business in the State of California.

7. That al times hereinafter mentioned, upon information and belief, Defendant, GLAXOSMITHKLINE, was and still is a corporation organized and existing under the laws of the State of Pennsylvania.

8. That at all times hereinafter mentioned, upon information and belief, Defendant, GLAXOSMITHKLINE, was and still is a foreign corporation authorized to do business in the State of California.

9. That at all hereinafter mentioned, upon information and belief, Defendant, GLAXOSMITHKLINE, was and still is a business entity actually doing business in the State of California.

10. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, was and still is a corporation organized and existing under the laws of the State of Pennsylvania and with its principal place of business in the state of Pennsylvania.

11. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, was and still is a foreign corporation authorized to do business in the State of California.

12. That at all times hereinafter mentioned, upon information and belief, Defendant, SMITHKLINE BEECHAM CORPORATION d/b/a GLAXOSMITHKLINE, was and still is business entity actually doing business in the State of California.

13. That at all times hereinafter mentioned, upon information and belief, Defendant presently markets and sells the drug Avandia.

14. That at all times hereinafter mentioned, upon information and belief, Defendant engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Avandia, and in pursuance of this business, transacts business within the State of California and contracts to provide goods and services in the State of California.

15. That at all times hereinafter mentioned, upon information and belief, Defendant committed a tortious act, which caused the injury to Plaintiff, citizen of the State of California.

16. That at all times hereinafter mentioned, upon information and belief, Defendant committed a tortious act outside the State of Texas, which caused injury to Plaintiff, citizen of the State of California.

17. That at all times hereinafter mentioned, upon information and belief, Defendant regularly does and solicits business and engages in a persistent course of conduct in the State of California, deriving substantial revenue from goods and products consumed in the State of California.

18. That at all times hereinafter mentioned, upon information and belief, Defendant expects or should reasonably expect its acts to have consequences in the State of California, and derives substantial revenue from interstate or international commerce.

BACKGROUND
STATEMENT OF THE CASE

19. Type 2 diabetes is the most common form of diabetes, afflicting 18 million Americans and 200 million people worldwide. This form of diabetes occurs when the body does not make enough insulin (a hormone needed to convert sugar and other food into energy) or cannot effectively use what it manages to produce. Further, diabetics are prone to heart problems, and indeed, two-thirds of diabetics die of heart problems.

20. Avandia, created and marketed by GSK, is designed to treat persons with Type 2 diabetes by helping sensitize cells to insulin, thereby greatly assisting in blood-sugar control. It also is combined with metformin and sold as Advandamet. Only one other drug like it, pioglitazone, sold as Actos and Actoplus, Met by Takeda Pharmaceuticals, is sold in the United States. In 2006, Avandia represented 37% of the U.S. market for oral diabetes treatments. Thus, the U.S. market for such drugs is huge, and Avandia faces only one competitor for that market.

21. Avandia had a total U.S. sales of \$2.2 billion in 2006, slightly less than the \$2.6 billion in total U.S. sales for Actos, according to IMS Health, a healthcare information company. Approximately 13 million Avandia prescriptions were filled in the U.S. last year, with a one-month supply of Avandia selling for between \$90 and \$170. Avandia is critical to GSK, being the company's second largest selling drug after Advair (an asthma medication).

22. GSK's product Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death. In 2005, GSK performed an overview analysis of multiple Avandia trials, referred to as a "meta-analysis", and shared the preliminary results with the Food and Drug Administration ("FDA") in September 2005. Almost one year later, in August 2006, a more complete version of the meta-analysis was provided to the FDA. The results of GSK's analysis showed that patients taking Avandia had a 31% higher risk of adverse cardiovascular events such as heart attack due to obstruction of blood flow.

23. GSK's Avandia can cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest and death. Not only was GSK aware of the dangers posed by Avandia, but data from these studies continued to be made available to GSK. On May 21, 2007, Dr. Steven E. Nissen, a prominent cardiologist associated with the Cleveland Clinic, published a study in the *New England Journal of Medicine* of his analysis of 42 studies comprising of approximately 28,000 people who took Avandia. These were on-line databases of GSK studies that were available on the Internet. Dr. Nissen's meta-analysis revealed a 43% higher risk of heart attack for those taking Avandia compared to people taking other diabetes drugs or no diabetes medication, and people taking Avandia suffered such adverse events at a rate of 1.99%, as opposed to 1.51% for other patients. Further, Dr. Nissen's analysis showed a 64% elevated risk of death from cardiovascular causes.

24. Despite GSK's longstanding knowledge of these dangers, Avandia's label only warns about possible heart failure and other heart problems when taken with insulin.

GSK failed to warn and disclose to consumers that Avandia significantly increased the risk of adverse cardiovascular events. Furthermore, the proper and effective use of Avandia by Plaintiff was impaired due to GSK's failure to warn of Avandia's defects and GSK's failure to properly and adequately set forth such warnings in Avandia's drug labeling.

25. GSK knew of these dangerous defects in Avandia from the many trials which it performed and to which it had access and from its own analysis of these studies, but took no action to adequately warn or remedy the defects, but instead concealed, suppressed and failed to disclose the dangers. Even in the face of Dr. Nissen's study, GSK continues to fail to warn of these dangers through revised drug labeling.

26. Not only has GSK failed to disclose in its labeling or advertising that Avandia is actually dangerous for diabetics, GSK has represented and continues to represent that they manufacture and/or sell safe and dependable pharmaceuticals with safety as their first concern:

Like all innovative pharmaceutical companies, we carry out a series of clinical trials to test each investigational drug for the potential to become a new medicine.

* * *

Phase I trials typically involve health volunteers. *These trials study the safety of the drug and its interaction with the body*, for example, its concentration and duration in the blood following various doses, and begin to answer such questions as whether the drug inhibits or amplifies the effects of other medicines that might be taken at the same time.

Phase II studies enroll patients with the illness an investigational drug is designed to treat. These trials evaluate whether the drug shows favourable effects in treating an illness and seek to determine the proper dose. They provide an opportunity to explore the therapeutic potential of the drug in what may be quite different illnesses. *The evaluation of safety continues.*

If Phase II results have been encouraging, Phase III trials, the largest part of a clinical-development program, go forward. *Phase III trials are designed to provide the substantial evidence of efficacy and safety required*, in addition to data from earlier-phase trials, before regulatory agencies will approve the investigational drug as a medicine and allow it to be marketed.

<http://www.gsk.com/research/clinical/index.html> (emphasis supplied).

27. GSK has also strongly touted their commitment to improving the quality of life: "We have a challenging and inspiring mission: to improve the quality of human life by enabling people to do more, feel better and live longer."

<http://www.gsk.com/about/index.htm>.

28. On May 21, 2007, the FDA issued a Safety Alert on Avandia showing that there is a potentially significant risk of heart attack and heart-related deaths in patients taking Avandia.

29. Based on these representations, upon which Plaintiff relied, including the omission from the Avandia labeling of the danger of increased risk of adverse cardiovascular events as a result of ingesting Avandia, Plaintiff purchased and ingested Avandia believing that the drug would be safe and effective.

30. In fact, however, Avandia poses significant safety risks due to defects in its chemical design and inadequate labeling.

31. To date, GSK has failed to warn or inform consumers, such as Plaintiff or Plaintiff's prescribing physician, of the known defects in Avandia that can lead to increased risks of cardiovascular events, including myocardial infarction, fraudulently concealed these defects and made misrepresentations to the damage and detriment of Plaintiff.

32. As a result of GSK's omissions and/or misrepresentations, Plaintiff ingested Avandia from approximately May 3, 2004 until January of 2006.

33. On or around January 18, 2006, Plaintiff suffered a myocardial infarction.

34. As alleged herein, as a direct and proximate result of the Defendant's negligence and wrongful conduct, and the unreasonably dangerous and defective characteristics of the subject product, the Plaintiff suffered a myocardial infarction. The Plaintiff had endured substantial pain and suffering. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. The Plaintiff has lost past earnings and has suffered a loss of earning capacity. The Plaintiff has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally and economically injured. The injuries and damages to Plaintiff are permanent and will continue into the future. The Plaintiff seeks actual and punitive damages from the Defendant as alleged herein.

COUNT I
PRODUCT LIABILITY – DESIGN DEFECT

35. Plaintiff repeats and reiterates the allegations previously set forth herein.

36. At all times material to this action, GSK was responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling Avandia.

37. The subject product is defective and unreasonably dangerous to consumers.

38. Avandia is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design and formulation.

39. That at all times hereinafter mentioned, the drug Avandia was not suited for the treatment of diabetes, and was not safe and effective for the treatment of diabetes, even though GSK directly and indirectly advertised, marketed and promoted Avandia for such use.

40. That at all times hereinafter mentioned, the drug Avandia was not safe and was not suited for the purposes for which GSK, directly and indirectly, advertised, marketed and promoted the drug at the time GSK designed, manufactured, distributed and sold the drug and placed the drug in the stream of commerce.

41. Avandia was defective and unreasonably dangerous when it left control of GSK in one or more of the following manners:

- a) The risk associated with use of Avandia far outweighed the utility derived from using the medication;
- b) Defendant's failed to provide adequate warnings regarding the hazards associated with the use of Avandia;
- c) Defendant's product was defectively designed and unreasonably dangerous in design and composition in that other medications could achieve similar results without the risks presented by Avandia; and
- d) Avandia failed to comply with express warranties that the product was safe and effective for human consumption.

42. In addition, at the time the subject product left the control of GSK, there were practical and feasible alternative designs that would have prevented and/or significantly reduced the risk of the Plaintiff's injuries and death without impairing the reasonably anticipated or intended function of the product. These safer alternative designs were economically and technologically feasible, and would have prevented or significantly reduced the risk of the Plaintiff's injuries without substantially impairing the product's utility.

43. As a direct and proximate result of the subject product's defective design, the Plaintiff suffered severe and permanent physical injuries, including but not limited to myocardial infarction. The Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The Plaintiff has suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from GSK as alleged herein

WHEREFORE, Plaintiff demands judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT II
PRODUCT LIABILITY – MANUFACTURING DEFECT

44. Plaintiff repeats and reiterates the allegations previously set forth herein.

45. At all time material to this action, GSK was engaged in the business of designing, developing, manufacturing, rebranding, labeling, marketing, distributing and/or selling Avandia.

46. At all times material to this action, Avandia was expected to reach and did reach, consumers in the State of California and throughout the State of California, including the Plaintiff herein without substantial change in the condition in which it was sold.

47. GSK sold and/or distributed Avandia in a condition that posed unreasonable risks from reasonably anticipated use. Avandia was expected to and did

reach Plaintiff without substantial change in condition from the time that it left the control of the Defendant.

48. The defective conditions alleged herein rendered Avandia unreasonably dangerous to the Plaintiff and proximately caused the injuries and damages for which this lawsuit seeks recovery.

49. At all times material to this action, Avandia was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by GSK in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but not limited to, one or more of the following particulars:

- a. When placed in the stream of commerce, Avandia contained manufacturing defects which rendered the product unreasonably dangerous;
- b. The subject product's manufacturing defects occurred while the product was in the possession and control of GSK;
- c. The subject product was not made in accordance with GSK's specifications or performance standards; and
- d. The subject product's manufacturing defects existed before it left the control of GSK.

50. As a direct and proximate result of the subject product's manufacturing defects, the Plaintiff suffered severe and permanent physical injuries, including but not limited to cardiac injury and subsequent death. The Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The

Plaintiff has suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from GSK as alleged herein

WHEREFORE, Plaintiff demands judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT III
PRODUCT LIABILITY – FAILURE TO WARN

51. Plaintiff repeats and reiterates the allegations previously set forth herein.
52. GSK knew, or in the light of reasonably available knowledge, should have known, of the danger in Avandia that caused the damage for which recovery is sought. The ordinary user or consumer of Avandia would not have realized such dangers.
53. GSK neglected to provide Plaintiff with warnings that reasonably could have been expected to catch the attention of a reasonably prudent person under similar circumstances taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product. Further, GSK failed to provide warnings which could accurately advise ordinary consumer of the scope, severity and likelihood of serious injury resulting from use of its product. Had such warnings been provided, the injuries and damages sustained by Plaintiff could have been avoided.
54. GSK neglected to provide Plaintiff's prescribing physician with adequate warnings to accurately advise such physician of the increased severity and likelihood of serious injury resulting from the prescribing and ingestion of Avandia to patients such as Plaintiff.

55. GSK's product failed to function as expected and there existed feasible design alternatives equally effective and useful that would have had a reasonable probability of preventing the harms sustained by Plaintiff.

56. That at all times hereinafter mentioned, upon information and belief, GSK assumed a strict products liability to persons using Avandia, including Plaintiff, who sustained injuries, harm and damages by reason of the use of Avandia for purposes directly and indirectly advertised, marketed, and promoted by GSK, including for the treatment of diabetes.

57. As a direct and proximate result of the subject product's defective and inappropriate warnings, the Plaintiff suffered severe and permanent physical injuries, including but not limited to myocardial infarction. The Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The Plaintiff has suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from GSK as alleged herein

WHEREFORE, Plaintiff demands judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IV
BREACH OF IMPLIED WARRANTY

58. Plaintiff repeats and reiterates the allegations previously set forth herein.

59. GSK designed, manufactured, marketed, distributed, supplied and sold the subject product for the treatment of diabetes.

60. At this time that the GSK manufactured, marketed, distributed, supplied and/sold Avandia, they knew of the use for which the subject product was intended and impliedly warranted it to be merchantable quality and safe and fit for such use.

61. The Plaintiff, individually and through his prescribing physician, reasonably relied upon the skill, superior knowledge and judgment of GSK.

62. The Plaintiff was prescribed, purchased and used the subject product for its intended purpose.

63. Due to the GSK's wrongful conduct as alleged herein, the Plaintiff could not have known about the nature of the risks and side effects associated with the subject product until after he used it.

64. Contrary to the implied warranty for the subject product, Avandia was not of merchantable quality, and was not safe or fit for its intended uses and purposes, as alleged herein.

65. As a direct and proximate result of GSK's breach of implied warranty, the Plaintiff suffered severe and permanent physical injuries, including but not limited to myocardial infarction. The Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from GSK as alleged herein

WHEREFORE, Plaintiff demands judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT V
NEGLIGENCE

66. Plaintiff repeats and reiterates the allegations previously set forth herein.

70. That at all times hereinafter mentioned, GSK was under a duty to exercise reasonable care in the design manufacture, testing processing, marketing advertising, labeling, packaging distribution, and sale of Avandia, and GSK knew or should have known that Avandia was not safe and that the user could sustain injuries and harm from the drug.

71. GSK negligently, recklessly, grossly negligently, wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that GSK, directly and indirectly, advertised, marketed and promoted Avandia for the treatment of diabetes, even though Avandia, in fact, not reasonably safe for such use, and furthermore, GSK failed to adequately warn of the increased risk of serious cardiovascular events which GSK knew or should have known about.

72. GSK was further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others by manufacturing, distributing, selling, advertising, marketing and promoting Avandia even though such drug was not safe or effective for any purpose because it caused serious cardio-vascular events and by failing to adequately warn the public of such risks.

73. The aforesaid incident and the injuries sustained by the Plaintiff were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including the Plaintiff, on the part of GSK in the design, manufacture, distribution, advertising, marketing and promoting of Avandia as being safe and effective in the treatment of diabetes, and by inducing the public, including the Plaintiff, and Plaintiff's prescribing physician, to believe that Avandia was effective in the treatment of the causes and symptoms of diabetes.

74. GSK failed to exercise reasonable care in the design, manufacture, testing, processing, marketing, advertising, labeling, packaging, rebranding, distribution and/or sale of Avandia in one or more of the following respects:

- a) Designing, marketing, processing, advertising, packaging, distributing and/or selling a product that defendants knew, or should have known, carried the risk of serious; life-threatening side effects;
- b) Failure to adequately test the product prior to placing the drug Avandia on the market;
- c) Failure to use care in designing, developing and manufacturing their product so as to avoid posing unnecessary health risks to users of such product;
- d) Failure to conduct adequate pre-clinical testing and post-marketing surveillance to determine the safety of Avandia;
- e) Failure to advise consumers, such as plaintiff, that consumption of Avandia could result in severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure and severe injury to the heart leading to cardiac arrest and death.
- f) Failure to advise the medical and scientific communities of the potential for severe and disabling side effects, including but not limited to heart injury, excessive fluid retention, fluid-overload

disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death.

- g) Failure to provide timely and/or adequate warnings about the potential health risks associated with the use of Avandia; and
- h) Any and all other acts of negligence with respect to Avandia which may be shown at trial.

75. That at all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by GSK was a proximate cause of injuries by the Plaintiff.

76. That at all times hereinafter mentioned, the Plaintiff did not contribute to his injuries by reason of any negligence or culpable conduct on the Plaintiff's part.

77. That as a result of the aforesaid occurrence, the injuries and subsequent death sustained by the Plaintiff resulting there from, the Plaintiff suffered extensive monetary and pecuniary losses and other compensatory damages were also incurred and paid out including necessary medical, hospital, and concomitant expenses. In addition, the Plaintiff was deprived of a chance for safe and effective and/or successful treatment.

78. As a direct and proximate result of GSK's carelessness and negligence, the Plaintiff suffered severe and permanent physical injuries, including but not limited to myocardial infarction. The Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from GSK as alleged herein

WHEREFORE, Plaintiff demands judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VI
BREACH OF EXPRESS WARRANTY

79. Plaintiff repeats and reiterates the allegations previously set forth herein.

80. That at all times hereinafter mentioned, upon information and belief, GSK, by direct and indirect advertising, marketing and promoting Avandia for the treatment of diabetes, and by placing this drug in the stream of commerce knowing that Avandia would be prescribed for the treatment of diabetes, in reliance upon the representations of GSK expressly warranted to all foreseeable users of this drug, including the Plaintiff, that Avandia was safe and effective for the treatment of diabetes.

81. GSK impliedly warranted in manufacturing, distributing, selling, advertising, marketing and promoting Avandia to all foreseeable users, including Plaintiff, that Avandia was safe and effective for the purposes for which it had been placed in the stream of commerce by GSK, including for the treatment of diabetes, and that Avandia was reasonably safe, proper, merchantable and fit for the intended purposes, including for the treatment of diabetes.

82. That at all times hereinafter mentioned, Plaintiff relied upon the aforesaid express and implied warranties by GSK.

83. That at all times hereinafter mentioned, Plaintiff's use of Avandia prior to and up to the time of the above-described incident was consistent with the purposes for which GSK directly and indirectly advertised, marketed and promoted Avandia, and Plaintiff's use of Avandia was reasonably contemplated, intended and foreseen by GSK

at the time of the distribution and sale of Avandia by GSK, and, therefore, Plaintiff's use of Avandia was within the scope of the above-described express and implied warranties.

84. GSK breached the aforesaid express and implied warranties because Avandia was not safe and effective for the treatment of diabetes, and because Plaintiff's use of Avandia for the treatment of diabetes, caused or contributed to the incident described herein.

85. As a direct and proximate result of GSK's breach of express warranty, the Plaintiff suffered severe and permanent physical injuries, including but not limited to myocardial infarction. The Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The Plaintiff suffered severe pecuniary loss. The Plaintiffs seek actual and punitive damages from GSK as alleged herein

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VII
VIOLATION OF CONSUMER LEGAL REMEDIES ACT

86. Plaintiff repeats and reiterates the allegations previously set forth herein.

87. The subject product is considered a "good".

88. GSK widely advertised and promoted Avandia as a safe and effective medication.

89. GSK knew, or should have known, that the subject product was unreasonable dangerous and defective, and had a propensity to cause serious and potentially life-threatening side effects.

90. GSK had a duty to disclose material information about serious side effects to consumers such as the Plaintiff. Additionally by virtue of GSK's partial disclosures about the medication, in which GSK touted Avandia as safe and effective treatment, GSK had a duty to disclose all facts about the risks of use associated with the medication, including the potential for the medication to cause cardiac death. GSK intentionally failed to disclose this information for the purpose of inducing consumers, such as the Plaintiff, to purchase GSK's dangerous product.

91. Had the Plaintiff been aware of the hazards associated with Avandia, the Plaintiff would not have purchased and/or consumed the product that lead proximately to the Plaintiff's injury.

92. GSK's advertisements regarding Avandia made material misrepresentations to the effect that Avandia was a safe and effective treatment, which these misrepresentations knew to be false by GSK, for the purpose of fraudulently inducing consumers, such as the Plaintiff, to purchase such product. The Plaintiff relied on these material misrepresentations in deciding to purchase and consume Avandia to his detriment.

93. The damages sustained by the Plaintiff were a direct and foreseeable result of, and were proximately caused by GSK misrepresentations, concealment and omissions.

94. GSK has violated the Consumer Legal Remedies Act, in that they made untrue, deceptive, and/or misleading representations of material facts, and omitted and/or concealed material facts from the public, including the Plaintiff herein, concerning the use and safety of the subject product.

95. GSK's practice of promoting the subject product created and/or reinforced a false impression as to its safety.

96. GSK's statements and omissions were made with the intent that the Plaintiff herein, and his prescribing physician, would rely on such statements and omissions.

97. GSK's conduct was willful, wanton, and reckless. Based on the intentionally dishonesty nature of the GSK's conduct, which was directed at the Plaintiff and the public generally, GSK should also be held liable for punitive damages.

98. The aforesaid promotion, statements and/omissions concerning subject product by GSK constitute an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or knowing concealment, suppression, or omission of material facts with the intent that others rely upon such concealment, suppression, or omission in connection with the sale or advertisement of merchandise or services by GSK, in violation of the Consumer Legal Remedies Act.

99. As a direct and proximate result of GSK's acts of consumer fraud, the Plaintiff suffered ascertainable loss – economic loss that includes the purchases of the subject product and additional out-of-pocket healthcare related costs – for which the GSK is liable to the Plaintiff for treble the actual damages.

100. As a direct and proximate result of GSK's acts of consumer fraud, the Plaintiff suffered severe and permanent physical injuries, including but not limited to myocardial infarction. The Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The Plaintiff suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the GSK as alleged herein.

WHEREFORE, Plaintiff demands judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT VIII
PUNIVTIVE DAMAGES

101. Plaintiffs repeat and reiterate the allegations previously set forth herein.

102. At all times material hereto, GSK knew or should have known that the subject product was inherently more dangerous associated with the medication, including the potential for the medication to cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death.

103. At all times material hereto, GSK attempted to misrepresent and did misrepresent facts concerning the safety of the subject product.

104. GSK's misrepresentations include knowingly withholding material information from the medical community and the public, including the Plaintiff herein, concerning the safety of the subject product.

105. GSK knew of the subject product's defective and unreasonably dangerous nature, as set forth herein, but continued to design, develop manufacture, market, distribute and sell it so as to maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff herein, in conscious and/or negligent disregard of the foreseeable harm caused by Avandia.

106. GSK intentionally concealed and/or recklessly failed to disclose to the public, including the Plaintiff herein, the potentially life threatening side effects of Avandia in order to ensure continued and increased sales.

107. GSK's intentional and/or reckless failure to disclose information deprived the Plaintiff of necessary information to enable him weigh the true risks of using the subject product against its benefits.

108. As a direct and proximate result of GSK's conscious and deliberate disregard for the rights and safety of consumers such as the Plaintiff, the Plaintiff suffered severe and permanent physical injuries, including but not limited to myocardial infarction. The Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The Plaintiff has suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the GSK as alleged herein.

109. The aforesaid conduct of GSK was committed with knowing, conscious, and deliberate disregard for the rights and safety of consumers, including the Plaintiff herein, thereby entitling the Plaintiffs to punitive damages in an amount appropriate to punish the GSK and deter them from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT IX
FRAUD

110. Plaintiff repeats and reiterates the allegations previously set forth herein.

111. GSK widely advertised and promoted Avandia as a safe and effective medication.

112. GSK had a duty to disclose material information about serious side effects to consumers such as the Plaintiff. Additionally by virtue of GSK's partial disclosures about the medication, in which GSK touted Avandia as safe and effective treatment, GSK had a duty to disclose all facts about the risks of use associated with the medication, including the potential for the medication to cause heart injury, excessive fluid retention, fluid-overload disease, liver damage, liver failure, and severe injury to the heart leading to cardiac arrest, and death. GSK intentionally failed to disclose this information for the purpose of inducing consumers, such as the Plaintiff, to purchase GSK dangerous product.

113. Had the Plaintiff been aware of the hazards associated with Avandia, the Plaintiff would not have purchased and/or consumed the product that lead proximately to the Plaintiff's myocardial infarction.

114. GSK's advertisements regarding Avandia made material misrepresentations to the effect that Avandia was a safe and effective treatment, which misrepresentations GSK knew to be false, for the purpose of fraudulently inducing consumers, such as the Plaintiff, to purchase such product. The Plaintiff relied on these

material misrepresentations in deciding to purchase and consume Avandia to his detriment.

115. The damages sustained by Plaintiffs were a direct and foreseeable result of, and were proximately caused by GSK's misrepresentations, concealment and omissions.

116. GSK's conduct was willful, wanton, and reckless. Based on the intentionally dishonesty nature of GSK's conduct, which was directed at the Plaintiff and the public generally, GSK should also be held liable for punitive damages.

117. Any applicable statutes of limitation have been tolled by GSK knowing and active concealment and denial of the facts alleged herein. The Plaintiff and other members of the public who were prescribed and ingested Avandia for the treatment of diabetes have been kept in ignorance of vital information essential to the pursuit of these claims, without any fault or lack of diligence on their part, and could not reasonably have discovered the fraudulent nature of GSK's conduct, and information and documents concerning the safety and efficacy of Avandia. Furthermore, due to the aforesaid allegations, Plaintiff may rely on the discovery rule in pursuit of this claim.

118. By reason of the foregoing, Plaintiffs sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against GSK in an amount to be determined upon the trial of this matter.

WHEREFORE, Plaintiff demands judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT X
NEGLIGENCE PER SE

119. Plaintiff repeats and reiterates the allegations previously set forth herein.
120. GSK has an obligation not to violate the law.
121. GSK has violated the Federal Food, Drug and Cosmetic Act, 21, U.S.C. 301, *et Seq.*, related amendments and codes and federal regulations promulgated thereunder, and other applicable state and federal laws.
122. The Plaintiff, as a purchaser and consumer of Avandia, is within the class of persons that statutes described above are designed to protect.
123. Injury due to false, misleading and/or reckless advertising and promotion, and misbranding, misleading products and as otherwise set forth in this complaint, is the specific type of harm these statutes are designed to prevent.
124. GSK is responsible to Plaintiff for injuries incurred for its violations of the statutes described above under the doctrine of negligence per se.
125. As a direct and proximate result of the negligence and negligence per se of GSK and each one individually and as a result of the GSK's actions and/or inactions as set forth in this complaint, the Plaintiff was caused to suffer severe and permanent physical injuries, including but not limited to myocardial infarction. The Plaintiff endured substantial conscious pain and suffering, both physical and emotional in nature. The Plaintiff incurred significant expenses for medical care and treatment, suffered lost wages and earning, and was otherwise physically, emotionally and economically injured. The Plaintiff has suffered severe pecuniary loss. The Plaintiff seeks actual and punitive damages from the GSK as alleged herein.

WHEREFORE, Plaintiff demands judgment against GSK, a sum which exceeds the jurisdictional limits of all lower courts which the jury would find to be fair, adequate and just, and in addition, Plaintiff seeks punitive and exemplary damages against Defendant in an amount to be determined upon the trial of this matter, together with costs and reasonable attorneys' fees.

COUNT XI
NEGLIGENT MISREPRESENTATIONS

- 126. Plaintiff repeats and reiterates the allegations previously set forth herein.
- 127. GSK represented and marketed Avandia as being safe and effective.
- 128. After GSK became aware of the risks of ingesting Avandia, however, GSK failed to communicate to the Plaintiff and other members of the general public, that the ingestion of this drug could have the increased risk of serious cardio-vascular events.
- 129. Therefore, Plaintiff brings this cause of action against GSK under the theory of negligent misrepresentation for the following reasons:
 - a) Plaintiff incorporates all facts and allegations previously stated in this Complaint;
 - b) GSK failed to warn the Plaintiff, and other consumers, of the defective condition of Avandia, as manufactured and/or supplied by GSK;
 - c) GSK, individually, and through its agents, representatives, distributors and/or employees, negligently misrepresented material facts about Avandia in that they made such misrepresentations when they knew or reasonably should have known of the falsity of such misrepresentations. Alternatively, GSK made such misrepresentations without exercising reasonable care to ascertain the accuracy of these representations;

- d) the above misrepresentations were made to the Plaintiff, as well as the general public;
- e) the Plaintiff and his healthcare providers justifiably relied on GSK's misrepresentations; and
- f) Consequently, the Plaintiff's ingestion of Avandia was to his detriment and to the detriment of each of the Plaintiffs. GSK's negligent misrepresentations proximately caused the Plaintiff's injuries and monetary losses.

130. WHEREFORE, Plaintiff demands judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

COUNT XII
UNJUST ENRICHMENT

131. Plaintiff repeats and reiterates the allegations previously set forth herein.

132. As an intended and expected result of their conscious wrongdoing, Defendants have profited and benefited from the purchases of Avandia by Plaintiff.

133. Defendants have voluntarily accepted and retained these profits and benefits, derived from the Plaintiff and others, with full knowledge and awareness that, as a result of Defendants' fraud and other conscious and intentional wrongdoing, Plaintiff did not receive a product of the quality, nature or fitness that had been represented by Defendants or that Plaintiff, as a reasonable consumer, expected.

134. By virtue of the conscious wrongdoing alleged in this Petition, Defendants have been unjustly enriched at the expense of the Plaintiff, who is entitled to in equity, and hereby seeks the disgorgement and restitution of Defendants' wrongful profits,

revenue and benefits, to the extent, and in the amount, deemed appropriate by the Court; and such other relief as this Court deems just and proper to remedy the Defendants' unjust enrichment.

WHEREFORE, Plaintiff demands judgment against Defendant GSK, in the amount in excess \$75,000.00, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action

LOSS OF CONSORTIUM

135. Plaintiff repeats and reiterates the allegations previously set forth herein.

136. At all times material hereto, LINDA SIMS was the spouse of the Plaintiff, and as such, lives and cohabited with the Plaintiff.

137. By reason of the foregoing, Plaintiff's spouse has been caused, presently and in the future the loss of her spouse's companionship, services, society and the ability of the marital association between husband and wife has been lost, and as such LINDA SIMS has been caused great mental anguish and suffering.

WHEREFORE, LINDA SIMS, demands judgment against GSK for compensatory, treble, and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against the Defendant as follows:

- a. Awarding actual damages to the Plaintiff incidental to the Plaintiff's purchase and use of Avandia in an amount to be determined at trial;
- b. Awarding treble and/or punitive damages to the Plaintiff;
- c. Awarding pre-judgment and post-judgment interest to the Plaintiff;
- d. Awarding the costs and the expenses of this litigation to the Plaintiff;

- e. Awarding reasonable attorneys' fees and costs to the Plaintiff as provided by law; and
- f. Granting all such other relief as Court deems necessary, just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all Counts and as to all issues.

Dated: January 17, 2008

Respectfully submitted,

Mark P. Robinson, Jr.

Mark P. Robinson, Jr.

Karen B. Menzies

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